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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LAM, ANN Y	

ART UNIT	PAPER NUMBER
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/537,292	HATTORI ET AL.	
	Examiner	Art Unit	
	ANN Y. LAM	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/2/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 5-9, 21, 23 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Knapp et al., 6,235,471.

Knapp et al. teach microfluidic devices that include chambers and channels, fluidly connected to allow transport of fluid among the chambers and/or channels of these devices. Knapp et al. also disclose that "fluidly connected" refers to a junction between two regions, e.g., chambers, channels, wells etc., through which fluid freely passes. Such junctions may include ports or channels which can be clear, i.e., unobstructed, or can optionally include valves, filters, and the like, provided that fluid freely passes through the junction when desired. See column 42, lines 12-35.

As to claims 1, 7, 20, the filter is equivalent to the claimed permeation limiting zone that is capable of limiting permeation of at least a part of particles flowing in a

liquid [i.e., particles larger than the openings of the filter]. It is noted that “where one or more second channels are branched out from said first channel” reads on a channel that is continuous, wherein the portion on one side of the filter is considered to be one channel and the portion on the other side of the filter is considered to be a second channel.

As to claims 2, 8, there is inherently a plurality of obstacles arranged as being spaced from each other (i.e., forming openings.) (It is noted that one contiguous element can be considered to be comprised of obstacles arranged as being spaced from each other.

As to claim 3, the filter allows only a part [portion] of the particles in the liquid to permeate through a gap between adjacent obstacles, i.e., particles that are larger than the gap.

As to claim 5, the filter will guide at least a part [portion] of the particles to either the first channel or second channel, depending on the arrangement thereof, [and depending on the size of the particles relative to the size of the openings of the filter.

As to claims 6, 9, the obstacles are inherently formed in a two-dimensional manner. The term “periodically arranged” relates to method of manufacturing, and since the claim is directed to a device, the prior art only needs to disclose the same structural elements.

As to claim 21, Knapp et al. disclose that the substrate typically includes a detection window or zone at which a signal is monitored. This detection window typically includes a transparent cover allowing visual or optical observation and

detection of the assay results. Example detectors include spectrophotometers, photodiodes, microscopes, scintillation counters, cameras, etc. and examples of suitable detectors are widely available from a variety of commercial sources known to persons of skill. See column 53, lines 40-53.

As to claims 23-24, Knapp et al. disclose that the device includes a size separation zone for separating products by size. In one embodiment, the apparatus will include a substrate such as a membrane having, e.g., 4,096 spots (i.e., all possible 6-mer primers). Knapp et al. state that similarly, components in diagnostic or drug screening assays can be stored in the well or membrane format for introduction into the analysis region of the device, and that arrays of nucleic acids, proteins and other compounds are also used in a similar manner. See column 7, line 45 to column 8, line 16. Thus Knapp et al. teach a screening assay by binding proteins to membrane spots or providing a separation zone for proteins.

Claims 1- 3, 5-9 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by O'Connor et al. 6,729,352.

As to claims 1, 7, 20, O'Conner discloses that a filter in a microfluidic device can be porous beads or a mesh, for trapping materials in a fluid. See column 16, lines 30-44.

As to claim 1, the filter is equivalent to the claimed permeation limiting zone that is capable of limiting permeation of at least a part of particles flowing in a liquid [i.e., particles larger than the openings of the filter]. It is noted that “where one or more channels branched out from said main channel” reads on a channel that is continuous, wherein the portion on one side of the filter is considered to be one channel and the portion on the other side of the filter is considered to be a second channel.

As to claims 2, 8, the elements forming the porous bead or the mesh are the plurality of obstacles arranged as being spaced from each other (i.e., forming openings.) (It is noted that one contiguous element can be considered to be comprised of obstacles arranged as being spaced from each other. Also, a plurality of porous beads that are not adjacent each other are considered to be a plurality of obstacles arranged as being spaced from each other.

As to claim 3, the filter allows only a part [portion] of the particles in the liquid to permeate through a gap between adjacent obstacles, i.e., particles that are larger than the gap.

As to claim 5, the filter will guide at least a part [portion] of the particles to either the first channel or second channel, depending on the arrangement thereof, [and depending on the size of the particles relative to the size of the openings of the filter.

As to claims 6, 9, the obstacles are inherently formed in a two-dimensional manner. The term “periodically arranged” relates to method of manufacturing, and since the claim is directed to a device, the prior art only needs to disclose the same structural elements.

Claims 11-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Agrawal et al., 7,195,872.

As to claim 11, Agrawal et al. teach increasing the surface area of a substrate of a bioreactor, such as the surfaces of reservoirs on which reactions occur (col. 26, lines 14-34 and see fig. 2A.) Agrawal et al. teach that the plurality of microfeatures may comprise a pit, a trench, a pillar, a cone, a wall, a micro-rod, a tube, a channel or a combination thereof. The plurality of microfeatures may comprise communicating microfeatures. See column 4, lines 50-61. Agrawal et al. contemplates usage of the invention in a channel (see for example discussion of figure 3.) The trenches are inherently capable of guiding a part of particles to a predetermined direction since the trenches can be formed in the channel, wherein fluid with particles can be flowed. It is noted that the claim does not recite how the trenches guide the particles.

As to claim 12, the plurality of microfeatures may be distributed uniformly on the surface of the substrate. See column 4, lines 59-61.

As to claim 13, Agrawal et al. teach that the sizes of the microstructures (forming the textured surfaces) are chosen based on the desired effect (e.g., promoting fractionation, or blocking a compound or molecule of a particular size) (col. 27, lines 8-21.) Agrawal et al. also teach that the spacing (distance) between adjacent microstructures may be graduated from the inlet to the outlet (e.g., going from larger to

smaller) to trap different sized particles at different places to provide a filtering effect (col. 27, lines 21-25.)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 22 and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knapp et al., 6,235,471.

The disclosure of Knapp et al. has been discussed above.

More specifically, as to claims 22, 25, 26, 27, Knapp et al. disclose that the substrate typically includes a detection window or zone at which a signal is monitored. This detection window typically includes a transparent cover allowing visual or optical observation and detection of the assay results. Example detectors include spectrophotometers, photodiodes, microscopes, scintillation counters, cameras, etc. and examples of suitable detectors are widely available from a variety of commercial sources known to persons of skill. See column 53, lines 40-53. Knapp et al. also disclose in the background section of the patent, that mass spectrometry is also another detection techniques known in the art of microfluidics. See column 1, lines 27-38.

However, Knapp et al. do not specifically list mass spectrometry as one of the detection techniques that may also be used in combination with the microfluidic device disclose. The skilled artisan however would recognize that mass spectrometry may also be incorporated into the disclosed microfluidics, since it is a well known detection technique in the art, as discussed in the background section.

As to claim 25, Knapp et al. do not disclose a method of using the device to detect separated proteins that are decomposed by protease treatment. However, Knapp et al. teach that because of the breadth of the available sample storage formats for use with the present invention, virtually any set of reagents can be sampled and assayed in an integrated system of the present invention. For example, enzymes and substrates, receptors and ligands, antibodies and ligands, proteins and inhibitors, immunochemicals and immunoglobulins, proteins, etc., can all be assayed using the integrated systems disclosed. See column 31, lines 3-20. Separating proteins decomposed by protease treatment is well known in the art and utilizing the Knapp et al. device to provide the assay steps, including identification, is suggested by Knapp et al. As to the detector being a mass spectroscope, this has been discussed above regarding claim 22.

As to claim 27, washing the surface where molecules have been captured is well known in the art to remove unbound material.

Claims 4 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Connor et al., 6,729,352.

O'Connor has been discussed above.

As to claim 4, O'Connor et al. disclose porous beads and mesh to be examples of filters but do not disclose that the direction of force causing flow of the particles lies non-parallel with direction of arrangement of the obstacles at the front-most plane on the filter at the front-most plane on the branching point side of the filter. However, providing a mesh perpendicular, i.e., non-parallel, to the fluid flow direction is well known in the art as such configuration will serve to filter out the desired materials.

As to claim 10, O'Connor does not disclose that a gap between the adjacent obstacles of the filter in the direction of formation of the main channel differs from that in the direction of formation of the side channel. However, providing a channel that is non-linear is well known in the art and a filter in such a channel wherein the filter is perpendicular to the channel portion at which the filter is located is a well known configuration and thus is an obvious configuration to the ordinary artisan. Such a filter and channel combination forms a gap as recited by Applicants.

Claims 15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knapp et al., 6,235,471, in view of Sundberg et al., .6,086,825.

The disclosure of Knapp et al. has been discussed above. Additionally, Knapp et al. disclose that the microfluidic device has a material transport system for controllably transporting a material through and among the reagent introduction channel and reaction channel. For example, the material transport system can include electrokinetic, electroosmotic, electrophoretic or other fluid manipulation aspects (micro-pumps and microvalves, fluid switches, fluid gates, etc.) which permit controlled movement and mixing of fluids. See column 5, lines 4-39. (The electrokinetic transport system comprises the claimed first drive means for migration speed in one direction and a second drive means for migration speed in a different direction since differently charged particles will move in different directions.).

However, Knapp et al. do not disclose a width of entrance to the filter to be narrower than the width of the filter zone.

Sundberg et al. however disclose microfluidic substrates having channels varying in cross-sectional dimension so that capillary action spreads a fluid only within a limited portion of the channel network. In another aspect, the introduction ports may include a multiplicity of very small channels leading from the port to a fluid channel, so as to filter out particles or other contaminants which might otherwise block the channel at the junction between the channel and the introduction port. See abstract.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a width of entrance to the filter that is narrower than the width of the filter zone as may be desired as disclosed by Sundberg et al. for purposes such as limiting the spread of capillary action or blocking contaminants.

As to claims 16-17, the types of particles is not recited as part of the claimed device and relates to intended use. The Knapp et al. filter is capable of filtering the recited particles, depending on the size of the particles.

As to claim 18, the Knapp et al. micro-pumps or microvalves are capable of functioning to introduce a suspension of particles and diluting the suspension [with a fluid].

As to claim 19, the step of desalting is a method step and the claims are directed to a device rather than a method. The Knapp et al. device is capable of desalting the suspension since it has micro-pumps and microvalves for introducing a desalting medium.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Agrawal et al., 7,195,872.

Agrawal et al. has been discussed above.

More specifically, Agrawal et al. teach that the sizes of the microstructures (forming the textured surfaces) are chosen based on the desired effect (e.g., promoting fractionation, or blocking a compound or molecule of a particular size) (col. 27, lines 8-21.) Agrawal et al. also teach that the spacing (distance) between adjacent microstructures may be graduated from the inlet to the outlet (e.g., going from larger to smaller) to trap different sized particles at different places to provide a filtering effect

(col. 27, lines 21-25.) Thus, Agrawal et al. teach that the microfeatures or microstructures can be treanches and can have a spacing that is graduated. This is equivalent to trenches which differ in geometry of opening or pitch of the trenches. However, Agrawal et al. do not teach that the plurality of patterns (which differ in geometry of opening or pitch of the trenches) are formed with mirror symmetry in the filter portion. Given that Agrawal et al. suggest that various configurations of the microfeatures and microstructures can be provided, such as trenches, providing such trenches such that they form a pattern with mirror symmetry (along the longitudinal axis of the channel) would have been obvious to the skilled artisan as such configuration would serve the same purposes as disclosed by Agrawal et al., and such symmetry would produce a more regular pattern, as may be desirable for the intended purpose of the user.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANN Y. LAM whose telephone number is (571)272-0822. The examiner can normally be reached on Mon.-Fri. 10-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ann Y. Lam/
Primary Examiner, Art Unit 1641